Schedule of Accreditation

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Liverpool University Hospitals NHS Foundation Trust, trading as Quality Control North West - Liverpool

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Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Address Pharmacy Practice Unit 70 Pembroke Place Liverpool L69 3GF **Local contact** Mr C Newman Tel: +44 (0)151 794 8130 Fax: +44 (0)151 794 8108 Email: chris.newman@liverpoolft.nhs.uk Website: www.qcnw-liverpool.nhs.uk/	**Testing:** Chemical and Physical Microbiological Customer site work	L

Site activities performed away from the locations listed above:

Location details	Activity	Location code
Pharmaceutical manufacturing premises and associated clean rooms and workplace environments	Sampling of air, surfaces and water at clients premises Testing air quality for physical and microbiological quality at clients premises	Site

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
DRUGS, MEDICINES AND PHARMACEUTICALS	<u>Chemical and Physical Tests</u> As appropriate for the product category as detailed in relevant Pharmacopoeial Monograph	Specifications and methods detailed in the British Pharmacopoeia (BP), or documented in-house methods that have been validated in accordance with RDP013 and meeting the traceability requirements of QP8.3, using the following BP techniques and/or equipment:	
	Identification Tests Assay of active and non-active ingredients: Related substances tests	a) Ultra-violet and visible spectroscopy with reference to SOP015	L
	Qualitative reactions and tests	b) HPLC with UV detection (SOP139, SOP108, SOP073, SOP127)	L
		c) Volumetric techniques: Aqueous titration (SOP007)	L
	Density: Relative Density, Apparent Density and Weight per ml	SOP006 using automated densitometers	L
	Dissolution of tablets, capsules and suspensions	Paddle method (SOP036)	L
	Optical rotation	SOP017	L
	Particulate contamination	Sub visible particle counting by light obscuration method (SOP137)	L
	pH	pH meter (SOP111)	L
	Uniformity of weight	SOP024	L

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
DRUGS, MEDICINES, PHARMACEUTICALS, MEDICAL DEVICES, PHARMACEUTICAL AND PURIFIED WATER	<u>Microbiological Tests</u> As appropriate for the product category as detailed in relevant Pharmacopoeial Monograph	Documented in-house methods based on specifications and procedures detailed in the British Pharmacopoeia (BP),	
	Sterility testing	SOP383 supported by SOP422 using direct inoculation or SOP386 membrane filtration techniques as appropriate for product type, and SOP442 to characterise any isolates	L
	Total viable aerobic colony count at 20-25°C and at 30-35°C	SOP443 using spread plate, with enrichment step in TSB for low level recovery, or membrane filtration techniques as appropriate for product type, followed by SOP442 to characterise any isolates	L
Cytotoxic Drugs	Sterility testing	SOP401 in conjunction with SOP383 using direct inoculation technique and SOP442 to characterise any isolates	L

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
ENVIRONMENTAL SAMPLES Samples for hygiene monitoring purposes from controlled environments for pharmaceutical manufacturing:	<u>Microbiological Tests</u>	Documented In-House Methods:	
Contact plates from surfaces Finger imprint plates (finger plates) Plates or strips from active air samples Settle plates	Isolation, Enumeration and Characterisation of microbial contamination levels using Gram stain, Oxidase test, Catalase reaction, Spore stain, Motility test and methylene blue wet preparation for moulds	SOP440 supported by local procedures for sample processing and SOP442 to characterise any isolates	L
Samples to monitor hygienic handling practices in controlled environments for pharmaceutical manufacturing:			
Universal Operator Validation Kits; Radiopharmacy generator eluates and kits; Broths for operator/ process validation	Confirmation of sterility	Procedures for sample processing, subculture by streaking and assessment of results followed by SOP442 to characterise any isolates	L
Waters	Assessment of microbial loading/total viable count	a) SOP440 incubation of 1ml spread plate supported by local procedures for sample processing and SOP442 to characterise any isolates	L
		b) SOP443 aerobic colony count at 20-25°C and 30-35°C using membrane filtration	L

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
ENVIRONMENTAL SAMPLES (cont'd)	<u>Sampling for Microbiological Testing</u>	Documented In-House Methods:	
Clean Rooms and associated controlled environments	Air for microbial contamination	SOP440 supported by procedures for using active air samplers	Site
	Surfaces for microbial contamination	SOP440 supported by procedures using contact plates or swab technique	Site
	<u>Physical Tests</u>	Documented In-House Methods:	
Clean Rooms and associated controlled environments Cytotoxic cabinets LAF cabinets Safety cabinets	HEPA filter integrity testing/ installation leak testing	Dispersed oil particle technique documented as SOP379,in accordance with (EN ISO 14644-3:2019)	Site
	Particle counting for classification and monitoring of clean rooms	SOP440 based on EN ISO 14644-1:2015 and the Orange Guide (Rules and Guidance for Pharmaceuticals Manufacturing and Distribution 2017) using laser particle counters	Site
END			